PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, October 26, 1999, 10:00 A.M., Massachusetts Department of Public Health, 250 Washington Street, Floor 2, Boston, Massachusetts. Present were: Dr. Howard K. Koh (Chairman), Dr. Clifford Askinazi , Ms. Shane Kearney Masaschi, Mr. Benjamin Rubin, Mr. Albert Sherman, Ms. Janet Slemenda, Mr. Joseph Sneider, Dr. Thomas Sterne; and Mr. Manthala George, Jr. was absent. Also in attendance was Ms. Donna Levin, General Counsel.

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Chairman Koh announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A 1/2.

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The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management; Ms. Priscilla Neves, Division of Food & Drugs; Dr. Paul Dreyer, Director, Division of Health Care Quality; and Ms. Joyce James, Director, Determination of Need Program.

PERSONNEL ACTIONS:

In a letter dated October 7, 1999, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of the appointment of Carl Marci, M.D. to the affiliate medical staff of Tewksbury Hospital. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointment of Dr. Marci to the affiliate medical staff of Tewksbury Hospital be approved for a period of two years beginning October 1, 1999 to October 1, 2001:

APPOINTMENT	STATUS/SPECIALTY	MEDICAL LICENSE NO.
Carl Marci, M.D.	Psychiatry	159671

In a letter dated October 14, 1999, Blake Molleur, Executive Director, Western Massachusetts Hospital, Westfield, recommended approval of the appointment and reappointments to the consulting medical staff of Western Massachusetts Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the

recommendation of the Executive Director of Western Massachusetts Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointment and reappointments to the consulting medical staff of Western Massachusetts Hospital be approved as follows:

APPOINTMENT	**SPECIALTY**	**MEDICAL LICENSE NO.**
Howard C. Lederman, M.D.	Psychiatry	81248

REAPPOINTMENTS	**SPECIALTY**	**MEDICAL LICENSE NO.**
Philip T. Glynn, M.D.	Oncology/Hematology	35736
Alan D. Sampson, D.M.D.	Dentistry/Oral Surgery	10596

INFORMATIONAL BRIEFING ON PROPOSED REGULATIONS TO THE STATE SANITARY CODE CHAPTER X – MINIMUM STANDARDS FOR FOOD ESTABLISHMENTS – 105 CMR 590.000:

Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management, made introductory remarks. She said in part, "…Fourteen years ago, we were one of the first states in the country to develop a food code that was a unified code that would apply to both retail food stores and food service establishments. There have been marked changes that have occurred in the sale and service of food, be it through grocery stores, restaurants, or vending machines, over the last ten or fifteen years as more and more food preparation and food processing is actually occurring in retail settings as people spend more of their time out of the house and rely upon the convenience of already prepared or semi-prepared food products. What you see before you is a code that in all will be about 250 pages. About 50 pages will be state code provisions that are necessary for either administration and enforcement purposes, or because we have certain laws on the books that include certain definitions or require us to include certain components that aren't in the Federal Model Code. The Federal Model Code has about 200 pages of standards in it."

Ms. Priscilla Neves, Sanitarian, Division of Food and Drugs, addressed the Council. She stated in part, "…This is the first major revision in fourteen years…The purpose of 590.000 is the prevention of food-borne disease, and it establishes the Minimum Sanitation Standards and the Safe Food Handling Operations for restaurants, supermarkets, nursing homes, hospitals, and any type of food service operation where food is distributed, served, and sold directly to the consumer….According to the CDC most food-borne illness outbreaks occur within the retail food segment. Why do we need to revise the code at this time? There have been a lot of changes in the food service industry, in food delivery systems, production and technology. We have had a number of widely publicized outbreaks over the years where E.coli has been implicated in ground beef and in apple cider. We have had cyclospora in raspberries and we have even had shigella sonnei in parsley. As a result of these changes and outbreaks, both government and the food industry have had to look closely at their traditional regulations and the manner in which we approach food safety."

Ms. Neves continued, "There have been a number of government initiatives around food safety. One of them has been the President's Safe Food Initiative, which includes the recommendation to adopt the Federal Food Code by reference. The Federal Food Code is a national food regulation model. It was developed by FDA with input from CDC, USDA, the food industry, consumer groups and academia. It's a living document, which means that it is revised and updated every two years through the National Conference for food protection. The Food Code is different in that it provides a state of the art risk based food safety system called Hazard Analysis Critical Control Point (HACCP)in Massachusetts, people will be working with both the Federal Food Code and the Mass. supplement (105 CMR 590.000). We have provided for you a comparison of both so that it is easier to use them. In the supplement, most of the provisions relate to administration and enforcement. There is a small number of provisions that relate to special food operations that are not in the Federal Food Code such as residential kitchens and mobile food operations and a few minor changes have been made to be more consistent with our policies here in Massachusetts…."

"The revisions, along with the Federal Food Code, highlight those risk factors that have been identified by CDC as being significant: inadequate cooking, improper holding, contaminated equipment and poor personal hygiene. The revision further establishes five key principles or public health interventions to protect consumer health. The first is demonstration of knowledge and it makes it very clear that food safety is a shared responsibility by both government and by the food industry. Food operators and food inspectors without professional credentials will be required to demonstrate knowledge of food safety and prevention of food-borne disease by passing a nationally recognized food protection management certification exam. There is a focus on employee health controls, controlling hands as a vehicle for food contamination. There are time and temperature parameters for controlling pathogens, and provisions about advising consumers about the potential hazards around consuming raw or under processed animal foods such as oysters. There is also a greater focus on food service operations which feed highly susceptible populations such as nursing infants and the elderly and the immune compromised in hospitals. We have been working with FDA and local health officers to make sure that training becomes available. We are excited about adopting this uniform national standard that we feel is going to provide very current and up-to-date practical, science-based information to prevent food-borne disease", concluded Ms. Neves.

Ms. Ridley noted that three public hearings are scheduled on these proposed regulations, one in Hyannis at the Massachusetts Health Officers Association Conference, one in Boston and one in Western Massachusetts. After the hearings, the regulations will return to the Council for a vote. **No Vote/information Only.**

FINAL REGULATION:

REQUEST FOR PROMULGATION OF AMENDMENTS TO THE HOSPITAL LICENSURE REGULATIONS 105 CMR 130.000 ET SEQ. GOVERNING THE DISPOSITION OF REMAINS FOLLOWING THE DEATH OF A FETUS:

Dr. Koh, Chairman, began the discussion on the disposition of fetal remains regulations. He said, "This is an issue that has generated public input, input that we have very much appreciated. There were public hearings held on this issue and written comments received and considered and now we are going to be hearing from Dr. Dreyer and Ms. Ridley on the status of these proposed amendments. After that, there will be questions and comments from Public Health Council members only. There will be no discussion from the floor and then there will be a vote whether to accept or not accept these proposed amendments."

Dr. Paul Dreyer, Director, Division of Health Care Quality, presented the final regulations on fetal remains to the Council. He said, "I am here today to request promulgation of amendments to hospital licensure regulations regarding the disposition of fetal remains following a fetal loss or miscarriage. We presented the proposed amendments to the Council in June and held a public hearing on July 23. The amendments as originally presented to the Council and as modified in response to the testimony we received at the hearing are in Attachment 1 of your Council packages. Let me give you a bit of background that explains how we arrived at the present regulation. The Massachusetts statute that defines the rights of parents regarding disposition of fetal remains following a fetal loss or miscarriage became effective in 1978. Since that time, many hospitals interpreted the statute as applying only to fetal deaths that occurred at twenty weeks of gestational age or greater. As a result of a complaint investigation, we issued several clarifications to hospitals on this point. We first determined that the statute applied to fetal remains regardless of gestational age. We then realized that the statute did not define a fetus, and that a fetus is defined medically as beginning after the tenth week of gestation, and accordingly we revised our interpretation of the statute to apply only after ten weeks gestational age. This interpretation of the statute was also not satisfactory because it set-up a situation where the rights of parents were dependent upon the age of the fetus. Many complained about the arbitrariness of this interpretation. As a result, we proposed amendments to the hospital licensure regulations to focus on parental choice, choice with respect to the disposition of remains, and choice with respect to receiving detailed information about hospital disposition policies. The amendments that we took to the public hearing had the following features. They required hospitals to develop written policies concerning disposition of remains, irrespective of the duration of the pregnancy. They required a written protocol that provides that following the fetal loss, irrespective of the duration of the pregnancy, the parent is informed (1) of the availability of counseling and how to access counseling services, and (2) of the parent's right to direct either burial entombment or cremation or hospital disposal of the remains; (3) in writing, that disposal of remains by the hospital will be in conformance with state law and hospital licensure requirements; and (4) of the availability of a written description of the hospital's policy with respect to the disposition of the remains if requested."

Dr. Dreyer continued, "The Council Members have discussed the testimony that we received at the public hearing and the changes that we recommended as a result of the testimony. We have eliminated the term, the phrase, termination of pregnancy. That was a loaded term that probably never should have been in the draft. We retained in the regulations the rights of parents to direct the disposition of the remains regardless of gestational age. We have required that the hospital provides additional detailed information regarding disposition practices on request, and we have defined a fetus as a fetus or an embryo for the purposes of these regulations to clear up the question of what a fetus means. We believe that these regulations provide parents maximum choice while being sensitive to the differing needs of parents in different situations. Under our proposal, parents are informed in writing that if they direct hospitals to dispose of fetal remains, that disposal will be consistent with hospital law and regulation, and are told that more detailed information on disposition is available on request if they wish it. Some would have us force on parents an explicit description of hospital disposition practices; but, as several individuals testified at the hearing, this is harsh or even cruel. We believe that the proposed regulations are a sensitive approach to the difficult and painful issue of fetal loss, and we request promulgation of the regulations as presented in Attachment 1 of the Council Memo."

Ms. Ridley added, "I can just summarize that I know that the regulations track and comply and conform with the law that is on the books. What is really important is the sensitivity and feelings of the parents and the proposal that we have laid out allows for parents to become actively involved in that choice of the amount of detailed information that is received while insuring that they are provided with ample and detailed opportunity to obtain that information."

Dr. Koh, Chairman stated in part, "If I can say as Commissioner, I want to thank everybody who has been involved in this process and discussing this very important issue. In my view, after the tragedy of pregnancy loss, a woman certainly deserves the opportunity for counseling, the opportunity to grieve, and the opportunity to have information provided to her as she chooses in a sensitive and compassionate way; and, in my view as Commissioner, these amendments provide all those opportunities to a grieving woman."

Council Member Slemenda said that she agreed that the correct process is in place and had staff clarify that the word "available" meant on the spot information would be provided to the woman if requested. Ms. Slemenda also asked if the information would be in multiple languages. Dr. Dreyer added that during licensure review visits or in a complaint investigation, issues such as (1) is the information available on the spot and (2) is it in the appropriate languages for the hospital service area would be reviewed.

After consideration, upon motion made and duly seconded, it was voted (unanimously): That the Request for **Promulgation of Amendments to the Hospital Licensure Regulations 105 CMR 130.000 et seq. Governing the Disposition of Remains Following the Death of a Fetus** be approved; that a copy of the amendment be attached and made a part of this record as **Exhibit Number 14,663;** and that the amendment be forwarded to the Secretary of the Commonwealth for promulgation.

DETERMINATION OF NEED:

MEMORANDUM: INFORMATIONAL BULLETIN ON ANNUAL ADJUSTMENTS TO DoN EXPENDITURE MINIMUMS:

Ms. Joyce James, Director, Determination of Need Program, presented the DoN informational bulletin of DoN expenditure minimums, which are adjusted annually (in compliance with M.G.L.c.111,s.25B ½) to the Council for approval. Marshall & Swift's statewide figures are used for the capital cost inflation and the average of DRI/McGraw-Hill hospital and nursing home figures is used as the basis for recalculating inflated operating costs. No discussion occurred.

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the **Informational Bulletin on Annual Adjustment to DoN Expenditure Minimums. as follows (effective September 1, 1999):**

Capital Cost Indices	**(Marshall & Swift):**	
	September 1998	September 1999
Region – East	1736.1	1792.8
Massachusetts	1.08	1.08

$$\frac{1792.8}{1736.1} \times \frac{1.08}{1.08} = 1.0327$$

Operating Costs	**(DRI/McGraw-Hill):**	
	3rd Quarter 1998	3rd Quarter 1999
Skilled Nursing	1.550	1.603
Hospital	1.180	1.210

$$\left(\frac{1.603}{1.550} + \frac{1.210}{1.180}\right)/2 = 1.0298$$

INFORMATIONAL BULLETIN: ANNUAL ADJUSTMENTS TO DoN EXPENDITURE MINIMUMS

Capital Expenditure

September 1, 1998	**Filing Year Beginning September 1, 1999**
$488,836[1]	$504,821
$977,675[2]	$1,009,645
$9,165,696[3]	$9,465,414

Operating Costs

September 1, 1998	**Filing Year Beginning September 1, 1999**
$526,471[4]	$542,160

Source: DoN Regulations 105 CMR 100.020, Expenditure Minimum

COMPLIANCE MEMORANDUM:

PREVIOUSLY APPROVED DoN PROJECT NO. 4-3951 OF CARITAS SOUTHWOOD HOSPITAL AND PROJECT NO. 4-3952 OF CARITAS NORWOOD HOSPITAL – Progress Report on compliance with conditions of approval for transfer of ownership:

[1] Medical, diagnostic or therapeutic equipment for non-acute care facilities

[2] Total capital expenditures, including medical, diagnostic or therapeutic equipment, for non-acute care facilities

[3] Capital expenditures for acute care hospitals and comprehensive cancer centers, excluding major movable equipment

[4] Annual operating costs including staffing costs for non-acute care facilities

Ms. Joyce James, Director, Determination of Need Program, presented the progress report of Caritas Southwood and Norwood Hospitals to the Council. Ms. James said, "I am today to present the findings and recommendations based on a review of the annual report submitted by Caritas Christi and the Neponset Valley Community Health Coalition and to measure the progress being made by Caritas in complying with certain conditions of approval relating to projects number 4-3951 and 4-3952, relating to the transfer of ownership of Caritas Norwood and Caritas Southwood which were previously owned by the Neponset Valley Health Care System. The reports, as well as the conditions of approval, were included in the package submitted to the Council. The conditions relate to four areas: free care, mental health service, staffing, and landfill. Staff finds that Caritas has complied with the provision of the condition that it allocate 2.6 percent of its gross patient service revenue to free care. Staff also notes that the 2.6 percent includes free care provided at Southwood as well as Norwood Hospital….Staff finds that Caritas has fully complied with the condition requiring the hospital to educate the public about the availability of free care at the hospitals and also promoting the uninsured and underinsured to enroll in the state's Mass. Health Program. Caritas reports a 30% increase in the number of enrollees in the Mass. Health Program. Staff commends the Coalition and Caritas in this remarkable collaboration."

Ms. James continued, "Staff finds that Caritas has made steady progress in complying with the mental health and landfill conditions and anticipates that in the future they will be in full compliance. There is one area of disagreement between the Coalition and Caritas
concerning mental health services. The Coalition is concerned that they did not have sufficient input in the decisions concerning consolidation of Caritas' Psychiatric Services. They also expressed some concern they might not have the kind of input they anticipated. Staff finds that Caritas has fulfilled its obligations concerning the mental health services conditions. Caritas has maintained 40 locked beds at the Caritas Southwood Hospital site when the condition actually called for 20 locked beds. The mental health condition further requires Caritas in collaboration with the Coalition to develop a mental health service plan to address issues such as exit services, counseling and job placement. Given the work that Caritas had done with regard to the free care condition, I am certain that they will continue to collaborate to get this mental health services plan completed."

Council Member Slemenda asked about reproductive services and Ms. James replied that the Coalition has done a satisfactory job in making information available to residents of the community on the availability of reproductive health services.

Ms. Delia O'Connor, President of Norwood and Southwood Hospitals, spoke briefly, stating that she deferred to the Coalition since they have an excellent relationship and are very satisfied with their progress to date and will certainly work with the Coalition on the mental health services plan.

Mr. Ray Breton, President, Neponset Valley Community Health Coalition, accompanied by Attorney Laurie Martinelli addressed the Council. Mr. Breton made the following points:

1. "The closing of Southwood Hospital was a fairly bitter pill for the Coalition to accept. On the other hand, the Coalition is pleased with the turn around of the Norwood Hospital, financially and also

with the new zip of the personnel of the hospital – the new purposefulness of the professional staff".

2. The Coalition is pleased that the hospital is in the hands of a Catholic institution which has a long term commitment to health care.

3. Staffing continues to be a critical area and the Coalition understands the problem and believes that Caritas is making a bona fide effort to correct those problems.

4. In terms of the landfill, the Coalition has no problem. That is going along according to the timetable and continuing the monitoring by DPH for another year until the construction part is done is advised.

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve **Staff's recommendation on Previously Approved DoN Project No. 4-3951 of Caritas Southwood Hospital and Project No. 4-3952 of Caritas Norwood Hospital** that Caritas submit in one year a progress report on its compliance with the conditions on mental health services, staffing, and landfill. And further that compliance with the mental health services condition be a collaborative effort between Caritas and the Coalition.

PREVIOUSLY APPROVED DoN PROJECT NO. 1-1304 OF BERKSHIRE HILLS NORTH NURSING HOME – Request for a significant change to increase the final capital costs:

Ms. Joyce James, Director, Determination of Need Program, presented the request by Berkshire Hills North Nursing Home for a significant change. Ms. James noted, "Staff is seeking the Council's approval of the increase in the final cost requested by Berkshire Hills North Nursing Home for Project No. 1-1304. These increases are above inflation, hence the need for Council's approval. The holder has submitted extensive documentation indicating that these costs were unseen and occurred during actual construction of the building, and staff's review of the documents and discussions with the applicant concurs….In conclusion, staff finds that the additional costs were unforeseen and based on past Council decisions were reasonable and therefore recommend the Council's approval."

The staff analysis indicated the following:

That the holder is requesting an additional $2,343,141 (April 1997 dollars) above inflation. The increases are for new construction, $1,794,890; depreciable land development, $52,375; architectural and engineering costs, $115,477; net interest expense during construction, $239,756; major movable equipment, $77,400; and costs of securing financing, $136,050. These increases were offset by decreases in land costs, $71,332 and pre- & post – planning and development, $1,475. The documentation submitted by the holder indicates that these additional costs were incurred during project construction. The additional costs for construction included the costs for the previously approved increase in GSF; building requirements by the town of Lee; and compliance with the February 28, 1998 State Building Code 6th edition. The $1,727,849 figure also included $398,851 for abnormal shortages and $118,558 for winter conditions requested by the holder. The holder reports that the Central Artery

construction contributes to inventory shortages, which delayed construction. To proceed with construction, the holder reported payment of premium price for steel/plank and drywall products and additional labor costs resulting from the delay. The holder also reports that the extreme climate in Western Massachusetts requires additional costs for heating, ventilation, and air conditioning. Staff notes that Marshall and Swift recognizes adjustments to construction costs for abnormal shortages and for heating, ventilation, and air conditioning in areas with extreme climate. The documentation submitted by the holder also shows that the additional costs for land development were for relocation of the parking lot. Additional architectural and engineering costs were structural, electrical and mechanical design, architectural supervision, site and engineering design and supervision, conservation consultants, and a landscape designer hired by the Town of Lee. Net interest expense during construction and costs of securing financing were actual additional costs paid by the holder based on the construction loan. The additional costs for major movable equipment were for additional therapy equipment. In reviewing the holder's request for the increase, Staff has examined whether the requested additional costs were reasonable in light of past decisions, were not foreseeable at the time the application was filed and were beyond the holder's control. Consistent with the Council's past decisions, staff finds that the additional costs were reasonable, could not have been reasonably foreseen and were not reasonably within the control of the holder.

After consideration, upon motion made and duly seconded, it was voted: (unanimously) [Council Member Sherman not present to vote] to approve the **Request by Previously Approved DoN Project No. 1-1304 of Berkshire Hills North Nursing Home**, based on staff findings to increase the final capital costs to $7,210,588 (April 1997 dollars). The MCE is for 35,542 GSF of new construction and does not include the 5,040 GSF construction costs for the 12 DoN –exempt beds. The costs are approved as follows:

Land Costs:		
Land Acquisition Cost	$	225,000
Site Survey and Soil Investigation		54,029
Total Land Costs:		279,029
Construction costs:		
Depreciable Land Development Cost		100,000
Construction Contract (including bonding cost)		5,172,029
Architectural & Engineering Costs		408,332
Pre- & Post-filing Planning & Development		56,074
Net Interest Expense During Construction		458,467
Major Movable Equipment		339,822
Total Construction Costs:		6,534,724
Financing Costs:		
Costs of Securing Financing		396,835
Total Financing Costs:		396,835
Total Estimated MCE	$	7,210,588

This amendment is subject to the following condition:

(1) All conditions attached to the original and amended approval of this project shall remain in effect.

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The meeting adjourned at 10:45 A.M.

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Howard K. Koh, M.D., M.P.H.
LMH Chairman, Commissioner of Public Health